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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,415	02/27/2004	Toru Yano	Q80109	4540
65565 SUGHRUE-26	7590 01/22/200 5550	7.	EXAMINER	
	LVANIA AVE. NW		TOSCANO, ALICIA	
WASHINGTON, DC 20037-3213			ART UNIT	PAPER NUMBER
	•	•	1712	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		01/22/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

•		Application No.	Applicant(s)			
		10/787,415	YANO ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Alicia M. Toscano	1712			
	- The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address			
	Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)[🛛	Responsive to communication(s) filed on 27 No.	ovembe <u>r 2006</u> .				
•	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.					
3)[	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition	on of Claims					
4)⊠ Claim(s) <u>1,7-9 and 11-13</u> is/are pending in the application.						
*	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)	5) Claim(s) is/are allowed.					
6)⊠	6) Claim(s) <u>1,7-9 and 11-13</u> is/are rejected.					
•	Claim(s) is/are objected to.					
8)[_]	Claim(s) are subject to restriction and/o	r election requirement.				
Application	on Papers	·				
9) 🗆 -	The specification is objected to by the Examine	r.				
· · · · · · · · ·	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	nder 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Coo and addition control action for a not of the continue copies flot received.						
Attachment			(070.440)			
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4)  Interview Summary Paper No(s)/Mail D				
3) Inform	nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	Patent Application .				

### **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 7-9 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue the citation bridging pages 5 and 6 of specification, namely "L-lacid acid and D-lactic acid for use in the invention are easily commercially available and any of commercial products having a purity of 50% to 95% can be used but easily available 90% lactic acid is preferred" provides the basis for the addition of the a limitation wherein the lactic acid polymer has an optical purity of at least 90%. Examiner disagrees. Nowhere in the specification is the phrase optical purity used or defined. One of ordinary skill in the art would not recognize the "purity" of a composition to mean "optical purity".

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 3. Claims 1, 7-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroki (WO 03/006550, US 6984443 is used as an Equivalent English Translation of the WO document) in view of Kumazawa (JP 2003-096285) and Terado (US 6140458).

Kuroki includes elements of the invention as disclosed in the action dated 6/27/06. Kuroki discloses the use of L-lactic acid or D-lactic acid but Kuroki does not disclose the use of mixtures of both, as required by the amended Claims.

Kamazawa includes elements of the invention as discussed in the action dated 3/9/06. Kamazawa discloses mixing D-lactic acid resins with L-lactic acid resins [0012]. This blend forms a polylactic acid stereo complex that has a high melting point, leading to a resin that has superior moldablity.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Kuroki, the use of a mixture of a L-lactic acid resin and a D-lactic

acid resin, as taught by Kamazawa, in order to create a molded article with superior moldability.

Kuroki also does not disclose the optical purity of the polylactic acid polymers. Terado discloses the production of polylactic acid polymers. Said lactic acid has an optical purity of at least 95%, preferably at least 98% (Column 12 Lines 52-53). High molecular weight polyesters with high optical purity are preferred because they can be molded within a shortened period of time and have excellent moldability and workability (Column 3 Lines 1-11)

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Kuroki the use of a high optical purity polymer, as taught by Terado, in order to decrease the molding time and to obtain a product which has excellent moldability and workability.

#### Conclusion

### Response to Arguments

- 4. Applicant's arguments with respect to claims 1, 7-9 and 11-13 have been considered but are most in view of the new ground(s) of rejection. Applicant argues the amended Claims is not longer met by the teachings of Kuroki. Examiner agrees, and makes new grounds of rejection above.
- 5. Applicants arguments and the submitted Declaration regarding the optical purity are noted, however it is the Examiners position that newly added amendments regarding optical purity are not supported in the specification.

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is 571-272-2451. The examiner can normally be reached on Monday to Friday 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 574-272-1000.

**AMT** 

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